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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,016	07/10/2001	David L. Thompson	P-9153.05	8319
27581 7:	590 11/18/2003		EXAMINER	
MEDTRONIC, INC.			JASMIN, LYNDA C	
710 MEDTRONIC PARKWAY NE MS-LC340			ART UNIT	PAPER NUMBER
MINNEAPOLI	IS, MN 55432-5604		3627	
			DATE MAILED: 11/18/200	3

Please find below and/or attached an Office communication concerning this application or proceeding.

·	Application No.	Applicant(s)				
		Applicant(s)				
Office Action Summany	09/902,016	THOMPSON, DAV	/ID L.\			
Office Action Summary	Examiner	Art Unit	Ţ			
	Lynda Jasmin	3627				
The MAILING DATE f this c mmunication apperiod for R ply	ppears on the cover s	neet with the corresp indence ad	aress			
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perio - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).  Status	I.  1.136(a). In no event, however  2. In the statutory minimuly  3. In apply and will expire SIX  3. It are the application to be	r, may a reply be timely filed um of thirty (30) days will be considered timely (6) MONTHS from the mailing date of this or ecome ABANDONED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 10	<u>July 2001</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ Thi	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
<ul> <li>4)  Claim(s) 1-32 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-21,23-26 and 30-32 is/are rejected.</li> <li>7)  Claim(s) 22 and 27-29 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers	·					
9) The specification is objected to by the Examir 10) The drawing(s) filed on 10 July 2001 is/are: a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the I	a) accepted or b) accepted or b) accepted or b) accepted in bed in acception is required if the control in the	abeyance. See 37 CFR 1.85(a). drawing(s) is objected to. See 37 CF				
Priority under 35 U.S.C. §§ 119 and 120						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bure * See the attached detailed Office action for a list 13) Acknowledgment is made of a claim for domest since a specific reference was included in the foreign language point 14) Acknowledgment is made of a claim for domest reference was included in the first sentence of the foreign language point 14) Acknowledgment is made of a claim for domest reference was included in the first sentence of the foreign language point 14) Acknowledgment is made of a claim for domest reference was included in the first sentence of	nts have been receivents have been received iority documents have au (PCT Rule 17.2(a) st of the certified copiestic priority under 35 lefirst sentence of the seriority under 35 lefirst sentence of the seriority under 35 lefirst sentence of the seriority under 35 left priority under 35 left priori	ed. ed in Application No e been received in this National )). es not received. U.S.C. § 119(e) (to a provisional pecification or in an Application has been received. U.S.C. §§ 120 and/or 121 since	l application) Data Sheet. a specific			
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) 🔲 No	terview Summary (PTO-413) Paper No( ptice of Informal Patent Application (PTC her:				

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#### **DETAILED ACTION**

#### Drawings

1. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

#### Claim Objections

2. Claim 2 is objected to because of the following informalities: at line 1, the term "an" should be --and--. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 4, 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Regarding claims 4 and 5, the word "means" is preceded by the word(s) "to analyze" and "to select" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

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### **Double Patenting**

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 17-20, 25, 26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because having an inventory and production control system synchronous with various phases of product manufacturing standard, customized and newly approved, modified/redesigned devices and utilizing an

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inventory management system to select a user-specific configuration based on customized order achieved the same end result of utilizing an information network in data communication with manufacturing.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-3, 5-21, 23-26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because having a device manufacturing and supply information management for customized features with customized data set and utilizing an inventory management system to select a patient-specific configuration based on customized order achieved the same end result of utilizing an information network to received patient specific data for manufacturing.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Allowable Subject Matter

9. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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10. Claims 22, 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record fails to explicitly teach or fairly suggest a signal differentiation process including means for analyzing cardiac waveforms in combination with selecting configuration to test a manufacturing IMD.

#### Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dr. David M. Anderson, "Spontaneous Build-To-Order" Copyright 2001, <a href="http://www.design4manufacturability.com">http://www.design4manufacturability.com</a> discloses the concept of quickly build standard customized products upon receipt of spontaneous orders without inventory or purchasing delays.

James Carbone, "Most OEMs Build-To-Order" April 1999, Purchasing Magazine
Online discloses a build to order model system in electronic original equipment
manufacturers.

Duffin et al. discloses a system and method for communication with a medical device implanted in an ambulatory patient and for locating the patient to monitor device function. The implanted device further includes a telemetry transceiver for communicating data between the device and an external patient communication control device.

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Krichen et al. discloses a system and method for transferring information from an implantable device to a remote location. A programmer is electrically connected to the implantable medical device and is capable of temporarily saving selected information related the IMD and transferring the selected information to a remote location.

Linberg discloses a system and method for remote invoicing and inventory control of medical components of an IMD system upon implantation into a patient.

Vrhel et al. (6,543,047 B1) discloses a build-to-order manufacturing method for producing custom configured computer system.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9326.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1113.